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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 10/783,950 | 02/19/2004 | Andrew C. Hiatt | EPI3009 (068904-0507) | 4806 |
| 30542 | 7590 | 11/16/2004 | EXAMINER | |
| FOLEY & LARDNER P.O. BOX 80278 SAN DIEGO, CA 92138-0278 | | | WESSENDORF, TERESA D | |
| | | | ART UNIT | PAPER NUMBER |

1639

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/783,950

Applicant(s)

HIATT ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 4,8-11, 13-24, drawn to a method for preparing an immunoglobulin binding protein array in plant cells that bind to a ligand (without forming disulfide bonds).
- II. Claims 1, 3, 12 drawn to a method for preparing an immunoglobulin binding protein array in plant cells that form one or more disulfide bonds with one or more polypeptides.
- III. Claims 1 and 5-7, drawn to a method for preparing an immunoglobulin binding protein array in plant cells comprising sexually crossing the plants.
- IV. Claims 25-34, 38-52, drawn to a method of preparing a heavy chain binding protein array in eukaryotic cells.
- V. Claims 35-52, drawn to a method for preparing a plant CHBP array.
- VI. Claims 53-63, drawn to a CHBP array in eukaryotic cells. (Note claims 60 and 61 are duplicates).

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VII. Claim 64, drawn to a composition comprising an array of encapsulated CHBPs.

VIII. Claim 65, drawn to a method for preparing a heavy chain binding protein array in eukaryotic cells.

IX. Claim 66, drawn to a CHBP.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV, V and VIII are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods using different components and steps that results in different compounds having possibly different effects and/or functions.

Inventions VI, VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different compositions or array or single compounds each having different compositions or components therein. For example the array of Group VI comprises

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at least two eukaryotic cells. Group VII can read on non-eukaryotic array. Group IX contains a single CHBP polypeptide not necessarily in an array.

Inventions (I, II, III, IV, V and VIII) and (VI, VII and IX) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different statutory subject matter i.e., different methods and different compounds/compositions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for Group I is not required for Groups II-IX, specifically the literature searches, restriction for examination purposes as indicated is proper.

Claims 1, 3, 12, 16, 25, 35, 43, 53, 58, 64 and 66 are generic to a plurality of disclosed patentably distinct species comprising species included in each of the generic structure.

For Group I-III, applicants are to elect a single species from each of the subgroups 1-3. For example, one single species

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of Immunoglobulin, one transforming step and one plant cell as follows:

1. Immunoglobulin molecules (as recited in claim 12):

- a. Heavy chain or fragments thereof
- b. Light chain or fragments thereof
- c. J chains
- d. Secretory components

Each of the species covered in each of a-d differs in structure and mode of action. A prior art reference anticipating one species would not render obvious the other species.

2. Step of transforming (as recited in e.g., claim 16):

- a. Agrobacterium-mediated transformation
- b. Chemically-induced DNA uptake
- c. Electroporation
- d. Solid particle intrusion
- e. Biolistics
- f. Microinjection
- g. Macroinjection
- h. Lipofection
- i. Viral infection.

Each of the species covered in each of a-i differs in mode of action or operation or steps. A prior art reference

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anticipating one species would not render obvious the other species.

3. Plant cells (as recited in claims 19, 21 and 24):

- a. Tobacco (a dicotyledonous plant cell)
- b. Arabidopsis
- c. Corn (a monocotyledonous plant cell)
- d. Lemna
- e. Rice
- f. *Chlamydomonas reinhardtii* (green algae cell).

Each of the species covered in each of a-f differs in kind and mode of action. A prior art reference anticipating one species would not render obvious the other species.

For Groups IV and V, applicants are to elect a single species from each of the subgroups 1-3. For example, one single species of Immunoglobulin, one CHBP and one cell (e.g., corn if the genus plant is elected) as follows:

1. Polypeptide of the amino acid sequences, if (ii) is elected only a single species of either 1 or 2 and if (iii) either with or without disulfide bond formation;

i. At least 75% identical to a constant region of a mu or alpha chain of a native Ig Heavy chain

ii. Multiple combining sites with at least one of the recited requirements of (1) or (2)

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iii. Binds to a ligand

iv. Disulfide bonds

v. At least 75% identical to a sequence of Ig J chain.

Each of the species covered in each of i-v differs in structure and mode of action. A prior art reference anticipating one species would not render obvious the other species.

2. CHBP (as recited in claim 31)

i. J chains

ii. Secretory components

iii. Light chain constant regions.

Each of the species covered in each of i-iii differs in structure and mode of action. A prior art reference anticipating one species would not render obvious the other species.

3. Cells: (Note that these are actually genus. A species of e.g., plant like corn or mammalian like rat is required.)

i. Plant

ii. Insect

iii. Mammalian

Each of the species covered in each of i-iii differs in structure and mode of action. A prior art reference anticipating one species would not render obvious the other species.

For Group V: (See the above comment as to the election of a single species).

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1. Polypeptide as recited above (only from i-ii).
2. Transformation step as recited under Groups I-III (2).
3. Plant cells as recited in Groups I-III(3) above.

Each of the species covered in each of the subgroups 1-2 differs in structure and mode of action. A prior art reference anticipating one species would not render obvious the other species.

For Group VI: (See the above comment as to the election of a single species)

1. Elect a single species from (a)-(d) of the polypeptide sequence. If (b) or (c) is elected, a single species of either (i) or (ii).

Each of the species covered in each of the polypeptide differs in structure and mode of action. A prior art reference anticipating one species would not render obvious the other species.

2. Cell as recited in Group IV, (3), above.
3. Plant cell, as recited above.

For Group VII: (See the above comment as to the election of a single species).

Elect a single species from (a)-(d) of the polypeptide sequence. If (b) or (c) is elected, a single species of either (i) or (ii).

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Each of the species covered in each of the polypeptide differs in structure and mode of action. A prior art reference anticipating one species would not render obvious the other species

For Group IX: (See the above comment as to the election of a single species).

Elect a single species from (a)-(c) of the polypeptide sequence.

If (b) or (c) is elected, a single species of either (i) or (ii)

Each of the species covered in each of the polypeptide differs in structure and mode of action. A prior art reference anticipating one species would not render obvious the other species

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

November 15, 2004